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10/731,881	12/09/2003	Carl D. Wahlstrand	1023-333US01	6687

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EXAMINER
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REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
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3766

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05/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/731,881

**Applicant(s)**

WAHLSTRAND ET AL.

**Examiner**

Jessica L. Reidel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-20,22-25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-17 and 23 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,18-20,22,24,25 and 28 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/30/2007.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Acknowledgment is made of Applicant's Amendment, which was received by the Office on March 12, 2007. Claims 3, 21 and 26-27 have been cancelled. Claim 28 is new and has been added. Claims 1-2, 4-20, 22-25 and 28 are pending.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on January 30, 2007 has been acknowledged and is being considered by the Examiner.

#### ***Drawings***

3. In view of the response filed March 12, 2007, the objections made to the Drawings in the Office Action of December 11, 2006 have been withdrawn. The Examiner accepts the replacement drawings.

#### ***Specification***

4. In view of the response filed March 12, 2007, the objections made to the Specification in the Office Action of December 11, 2006 have been withdrawn.

5. The newly submitted sections of the disclosure are objected to because of the following informalities: paragraph 0002 of Applicant's originally filed disclosure appears on page 1, line 20. The newly submitted amendments to the Specification denote this paragraph as appearing on page 2 of the originally filed disclosure. Appropriate correction is required.

***Claim Objections***

6. Claims 1 and 19 are objected to because of the following informalities: there appears to exist inadvertent typographical errors in the claims. For example, regarding Claim 1, the last two lines should be changed to read “wherein of the second and third components, at least one comprises or is coupled to the motion reduction element” in order to clearly define the limitations of the claim and to be grammatically correct. Similar changes should also be made to lines 7-9 of Claim 19. Appropriate correction is required.

***Allowable Subject Matter***

7. The indicated allowability of claims 6 and 25 is withdrawn in view of reference(s) to Berrang et al. (U.S. 6,358,281) (herein Berrang) and Engmark et al. (U.S. 2004/0082977) (herein Engmark). Rejections based on the cited reference(s) follow.

8. Claims 15-17 and 23 are allowed.

9. Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-2, 4-5, 7, 9, 18-20, 22, 24-25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Berrang. As to Claims 1-2, 4-5, 9, 19-20, 22 and 28, Berrang expressly discloses an implantable cochlear prosthesis, read as an implantable medical device comprising a plurality of interconnected modules (see Berrang Abstract and Fig. 1). Specifically, the implantable medical device of Berrang comprises a battery 18 module 2 and an electronics 21 module 3 (see Berrang Figs. 1-2 and column 11, lines 29-38). Modules 2 and 3 of Berrang comprise a medical grade epoxy housing 28, 31, respectfully (see Berrang column 11, lines 55-67 and column 12, lines 1-25). The implantable medical device of Berrang further comprises an overmold comprising a component of palladium, a component of gold and a component of titanium/platinum/medical grade silicone where the all three components at least partially encapsulates each of the housings 28, 31 and are located adjacent to at least one side surface of a respective one of the housings 28, 31 (see Berrang column 12, lines 20-25). Berrang further discloses that the implantable medical device comprises a bridge structure, read as a motion reduction element 6 within the overmold and between modules 2 and 3. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the bridge structure 6 of Berrang connects modules 2 and 3 together, thus the modules 2 and 3 are incapable of moving apart from one another, thus bridge structure 6 is capable of reducing relative motion between at least two of the modules 2

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and 3 and is interpreted as a motion reduction element 6. Berrang specifies that the components of the overmold also comprise or are coupled to motion reduction element 6 (see Berrang column 9, lines 58-62 and column 12, lines 20-25).

The Examiner notes an alternative interpretation of Berrang. Berrang expressly discloses an implantable cochlear prosthesis, read as an implantable medical device comprising a plurality of interconnected modules (see Berrang Abstract and Fig. 1). Specifically, the implantable medical device of Berrang comprises a battery 18 module 2 and an electronics 21 module 3 (see Berrang Figs. 1-2 and column 11, lines 29-38). Electronics 21 module 3 is housed by support disc 33 and battery 18 module 2 inherently comprises its own housing because the battery is a lithium ion or nickel metal hydride-type (see Berrang column 12, line 55). These batteries contain liquid electrolytes necessitating a housing. In this interpretation, the medical grade epoxy 28, 31 acts as a component of an overmold, the coating of gold layers acts as a component and the outer coating of either titanium/platinum or medical grade silicone acts as a component where all of the components at least partially encapsulates each of the housings of the modules 2 and 3 and are located adjacent to at least one side surface of the housings of modules 2 and 3 (see Berrang Figs. 1 and 2, column 11, lines 28-67 and column 12, lines 1-24). Berrang further discloses that the implantable medical device comprises a bridge structure, read as a motion reduction element 6 within the overmold and between modules 2 and 3. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the bridge structure 6 of Berrang connects modules 2

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and 3 together, thus the modules 2 and 3 are incapable of moving apart from one another, thus bridge structure 6 is capable of reducing relative motion between at least two of the modules 2 and 3 and is interpreted as a motion reduction element 6. Berrang specifies that the components of the overmold comprise or are coupled to motion reduction element 6 (see Berrang column 9, lines 58-62 and column 12, lines 20-25).

12. As to Claim 7, Berrang specifies that the motion reduction element 6 comprises a wire-like element of either gold or platinum (see Berrang column 9, lines 50-62).

13. As to Claims 18 and 24, Berrang expressly discloses that the implantable medical device comprises an implantable electrode array, read as an implantable neurostimulator 10 for stimulating auditory nerves (see Berrang Figs. 1 and 4, column 2, lines 28-38, column 6, lines 63-67, column 6, lines 1-10, column 9, lines 35-49 and column 14, lines 4-19).

14. As to Claim 25, Berrang expressly discloses an implantable cochlear prosthesis, read as an implantable medical device comprising a plurality of interconnected modules (see Berrang Abstract and Fig. 1). Specifically, the implantable medical device of Berrang comprises a coil 4 module 1, a battery 18 module 2 and an electronics 21 module 3 (see Berrang Figs. 1-2 and column 11, lines 29-38). Module 1 comprises a polymer housing 13 (see Berrang column 10, lines 18-39). Modules 2 and 3 of Berrang comprise a medical grade epoxy housing 28, 31, respectfully (see Berrang column 11, lines 55-67 and column 12, lines 1-25). The implantable medical device of Berrang further comprises an overmold comprising a component of palladium, a component of gold and a component of titanium/platinum/medical grade silicone where the all three components at least partially encapsulates each of the housings of the modules (see Berrang column 12, lines 20-25). Berrang further discloses that the implantable medical device

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comprises a bridge structure, read as a motion reduction element 6 within the overmold and between modules 2 and 3. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the bridge structure 6 of Berrang connects modules 2 and 3 together, thus the modules 2 and 3 are incapable of moving apart from one another, thus bridge structure 6 is capable of reducing relative motion between at least two of the modules 2 and 3 in at least one degree and is interpreted as a motion reduction element 6. The implantable medical device of Berrang further includes a flexible tether, read as a coupling module to couple module 1 to modules 2 and 3 (see Berrang Figs. 1 and 15-18 and column 6, lines 4-25).

15. Claims 1-2, 4, 6, 18-20, 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Engmark. The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As to Claims 1, 4, 19 and 22, Engmark expressly discloses an implantable medical device 10 comprising a plurality of interconnected modules, specifically battery module 20 and electrical module 28. It is inherent that battery 20 comprises a housing since Engmark specifies that a chemical battery may embody the battery 20. It is inherent that chemical batteries are



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those which that contain liquid electrolytes necessitating a housing. Electrical module 28 comprises numerous interconnected electrical components mounted on a circuit board, read as a housing 27 (see Engmark Figs. 1-3, page 2, paragraphs 19-21 and page 4, paragraph 40). The implantable medical device 10 of Engmark further comprises an enclosure or housing, read as an overmold 11 comprising components 12 and 14 that at least partially encapsulate each of the housings of modules 20 and 28 (see Engmark Fig. 7). The overmold 11 of Engmark further comprises components 24 and 26 that are located adjacent to at least one side surface of the housings of modules 20 and 28 and adhesive, read as motion reduction element 90, within the overmold 11 between modules 20 and 28. Components 14, 24 and 26 comprise or are coupled to motion reduction element 90 (see Engmark Fig. 7, page 3, paragraphs 29-35 and page 4, paragraphs 35-40).

16. As to Claim 2, 6 and 20, and in addition to the arguments previously presented, Engmark expressly discloses that motion reduction element of the device 10 further comprises a tab or portion, read as a motion reduction element 247 that protrudes from component 24 and a tab or portion, read as a motion reduction element 207 that protrudes from component 26 such that elements 247 and 207 interact to reduce relative motion between modules 20 and 28 associated with components 26 and 24, respectively (see Engmark Fig. 7 and page 3, paragraphs 3-34).

17. As to Claim 9, Engmark specifies that components 24 and 26 of the motion reduction element of the device 10 comprise an electronic grade plastic (see Engmark page 3, paragraph 32). It is inherent that electronic grade plastics comprise a polymer.

18. As to Claims 18 and 24, Engmark specifies that the implantable medical device 10 may be an implantable neurostimulator (see Engmark page 1).

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***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang. Berrang discloses the claimed invention as discussed above except the motion reduction element is not specified to comprise a fabric or a fiber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the motion reduction element comprise a fabric or a fiber, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

22. Claims 5 and 28 are rejected under 35 U.S.C. 103(a) as being obvious over Engmark. The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C.

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102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

23. As to Claim 5 and 28, Engmark disclose the claimed invention as previously discussed except it is not specified that a first component of the overmold comprise an elastomeric material and second and third components comprise a nonelastomeric material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the first component of the overmold comprise an elastomeric material and second and third components comprise a nonelastomeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

***Double Patenting***

24. In view of the response filed March 12, 2007, specifically in regards to the arguments and the Terminal Disclaimer filed, the objections Double Patenting rejections in the Office Action of December 11, 2006 have been withdrawn.

***Terminal Disclaimer***

25. The terminal disclaimer filed on March 12, 2007 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Conclusion***

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stutz, Jr. et al. (U.S. 5,873,899) teaches the use of foam support structures of a molded thermoplastic surrounding the components of an implantable medical device. Solom (U.S. 2003/0120320) teaches the use of component cases to house either a battery, electronics circuit module or even a capacitor module for adding additional insulation between modules in an implantable medical device.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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